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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,803	12/19/2000	Gary R. McLuen	NEI-00104	7285
28960 7590 09/18/2009 HAVERSTOCK & OWENS LLP 162 N WOLFE ROAD SUNNYVALE, CA 94086				
EXAMINER				
HANDY, DWAYNE K				
ART UNIT		PAPER NUMBER		
1797				
MAIL DATE		DELIVERY MODE		
09/18/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/742,803

Applicant(s)

MCLUEN ET AL.

Examiner

DWAYNE K. HANDY

Art Unit

1797

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-30, 35-38, 40, 42, 44-48 and 50-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-30, 35-38, 40, 42, 44-48 and 50-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notices of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 07/17/09 and 09/09/09 have been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 61 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 61 recites the limitation of a "unidirectional bottom opening". This is new matter. The term unidirectional does not appear in the Specification. The plain meaning of the term "unidirectional" is "functioning in a single direction" (Merriam-Webster's Online Dictionary). The vial is shown in Figure 6 and described on pages 13-14. It includes the bottom opening (640) covered by frit (620).

The frit (620) supports the glass, but does not prevent fluid flow in either direction. In addition, the opening (640) does not contain any structure which could be used to block flow in either direction. Therefore, the bottom opening of the vial functions in both directions and the limitation of a "unidirectional bottom opening" is not supported by the Specification.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 61 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 61 recites the limitation of a "unidirectional bottom opening". This is unclear. The term unidirectional does not appear in the Specification. The plain meaning of the term "unidirectional" is "functioning in a single direction" (Merriam-Webster's Online Dictionary). The vial is shown in Figure 6 and described on pages 13-14. It includes the bottom opening (640) covered by frit (620). The frit (620) supports the glass, but does not prevent fluid flow in either direction. In addition, the opening (640) does not appear contain any structure which could be used to block flow in either direction. Therefore it is unclear what structural feature of the bottom opening provides the unidirectional function now recited in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 27-29, 35-38, 40, 42, 44 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by McGraw et al. (5,368,823).
8. Claims 27-29, 35, 36, 38, 45-48, 50-54, 56 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Zuckerman et al. (5,240,680).
9. Claims 27-30, 35, 36, 38, 45-48 and 50-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Cargill et al. (5,609,826).

These rejections were maintained in the previous Office Action (mailed 06/09/09). They remain in effect. Please see Response to Arguments below.

Inventorship

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zuckerman et al. (5,240,680) in view of Cargill et al. (5,609,826). Zuckermann teaches a vial having a unidirectional bottom opening (See valve 30 in Figure 3). Zuckermann does not teach the support around the vial. Cargill teaches a reaction block having reaction vessels (See Figures 2A-4 and columns 7-8). The vessels include a protrusion (128) for aligning the vessels during insertion (column 7, lines 60-63). The Examiner considers the protrusion to meet the support limitation. It would have been obvious to one of ordinary skill in the art to combine the protrusion from Cargill with the vial of

Zuckermann. One would add the protrusion from Cargill to the vial of Zuckermann to provide an alignment feature on the vial as in Cargill.

Response to Arguments

13. Applicant's arguments filed 09/09/09 have been fully considered but they are not persuasive. Applicant has argued that McGraw does not teach a support around the vial. The Examiner agrees and has not rejected claim 61 under McGraw.

14. Applicant has argued that McGraw fails to anticipate the instant claims because McGraw does not show teach a direct fit between the vial (column) and cartridge (bulkhead). See Applicant's Arguments, pages 9-16. This argument is beyond the scope of the claims as written. As noted in the previous Office Action (paragraph 5); the vial of McGraw still meets this limitation (as do the vials of Zuckermann and Cargill). The claim as currently written does not include the hole of the cartridge or even the cartridge. Applicant has not claimed the cartridge. Applicant has claimed a "having an exterior dimension to fit directly within a receiving hole of a cartridge". Therefore, any vial that has an exterior dimension that allows it to fit directly in a hole will meet this limitation. Applicant is attempting to limit an element of the claimed device - an exterior dimension of the vial - by using another, unclaimed element - a cartridge hole. The Examiner submits that there is no structural limitation that is provided by this phrase. The vials/vessels of the prior art have a dimension that would allow them to fit directly into the receiving hole of a cartridge in a pressure tight seal. Therefore the vials of the

references meet that limitation.

15. Applicant has argued that Zuckerman teaches a multidirectional opening and not a unidirectional bottom opening (Applicant's arguments, pages 16-17). The Examiner respectfully disagrees and notes that the multidirectional valve may be closed such that fluid may only flow in one direction in the vial opening.

16. Applicant has argued that Zuckermann does not teach a solid support or the pressure tight seal (Applicant's arguments, pages 17-25). As noted above, the pressure tight seal is beyond the scope of the claim. The claim merely requires that the vial have an exterior dimension to fit directly in a receiving hole. This is what Zuckermann shows in Figure 3. The Examiner previously noted (See Paragraph 6 of the previous Action; Paragraph 7 of the Office Action mailed 12/05/08; Paragraph 6 of the Office Action mailed 12/12/07 and Paragraph 8 of the 3/21/07 Action) that Zuckermann does not show the solid support but their use is disclosed in columns 2 and 3.

17. Applicant has argued that Cargill does not teach a support that has a precise dimension that provides a pressure tight seal when the vial is placed in a cartridge. The Examiner respectfully disagrees and submits that the keying protrusion (128) on the vessel of Cargill meets the support limitation (Arguments, pages 25-26).

18. Applicant has argued (Arguments, pages 26-34) that Cargill does not teach a solid support or the pressure tight seal. As noted above, the pressure tight seal is beyond the scope of the claim. The claim merely requires that the vial have an exterior dimension to fit directly in a receiving hole. This is what Cargill shows in Figures 6-8. The Examiner previously noted (See Paragraph 8 of the previous Action; Paragraph 7 of the Office Action mailed 12/12/07 and Paragraph 9 of the 3/21/07 Action) that Cargill does not show the solid support but their use is disclosed in column 2 and at the end of column 7.

19. Applicant has also argued that because McGraw recites the use of a vacuum to draw the chemical through the column (McGraw, col. 2, lines 17-22), then this excludes the presence of a pressure tight seal (Applicant's Arguments, page 13). The Examiner respectfully disagrees and notes that McGraw is not using the vacuum to seal the vial to the bulkhead, but instead is simply using vacuum to empty the contents of the columns into the exit basin (17). Furthermore, the Examiner submits that if there wasn't a pressure tight fit between McGraw's vial and the opening (15) in the bulkhead (16), then the vacuum could not function to draw the chemicals through the columns to the exit basin (17).

20. Applicant has argued that the Examiner has either unilaterally dismissed the pressure tight seal limitation or not given it proper weight (Arguments, page 12; page 17; and page 26). This is not the case. The Examiner has stated that the Applicant's

arguments directed to the limitation of "an exterior dimension to fit directly within a receiving hole of a cartridge" are beyond the scope of the claim as written. This limitation is based upon an element – the receiving hole of the cartridge – which is not part of the claimed device. Therefore, the limitation of the "exterior dimension to fit directly within a receiving hole of a cartridge" is extremely broad. The dimension could be any shape or size - as long as the element is capable of fitting in a hole of a cartridge, it will meet this claim. Applicant has argued that the references do not show a vial placed directly into a cartridge; therefore, the vials do not meet this limitation. This is incorrect and the reason for Examiner's assertion that the argument is beyond the scope of the claim. For this particular limitation, the reference does not have to show the vial directly in a cartridge; it simply has to show a vial having "an exterior dimension to fit directly within a receiving hole of a cartridge". The Examiner submits that the lower portion of the vials in each of the references cited show just this feature – a round portion that could fit directly into a cartridge hole. See Figures 5 and 6 of McGraw, Figures 2 and 3 of Zuckermann, and Figure 2A of Cargill.

21. Applicant has also argued that Cargill does not teach polyethylene vial (Page 25 of Arguments). The Examiner directs Applicant to column 7, lines 36-44 of Cargill for a teaching of the use of polyethylene for the reaction vessel.

Conclusion

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DWAYNE K. HANDY whose telephone number is (571)272-1259. The examiner can normally be reached on M-F 11:00-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dwayne K Handy/
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

September 11, 2009

